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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,963	05/15/2007	Howard C Herrmann	UPN-4929	6859

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EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
01/06/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficemonitor@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,963	HERRMANN ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/19/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckberg et al (5,013,296) in view of Samson et al (6,267,747).

a. Regarding claims 1 and 3, Buckberg discloses a method and device for delivering cardioplegia solution to the coronary arteries including the following steps: Puncturing the ascending aorta between a clamp above the coronary arteries (while not shown, one of ordinary skill in the art would recognize that during antegrade cardioplegia delivery, the clamp would be positioned above the coronary arteries) and the aortic valve (Col.2 lines 51-54 and Col.4 lines 34 and 35) via a coaxial needle 11 inserted through the a lumen 34 of the cannula which

is removed after insertion of the cannula (Col.3 lines 37 and 38). The cannula 10 is inserted into the ascending aorta and includes a first lumen 34 for cardioplegia delivery.

While Buckberg substantially discloses the apparatus as claimed, it does not disclose a folded non-porous membrane to cover the aortic valve nor the use of such a membrane.

However, Samson discloses an aortic catheter that delivers cardioplegia fluid (Col.5 lines 64-66) but also uses a balloon to occlude blood flow in the aortic root (Col.6 lines 38 and 39) and prevents the aortic valve from experiencing significant retrograde fluid pressure (Col.11 lines 14-22).The balloon of Samson delivers cardioplegic solution via a porous band of material 126 in the balloon, however, one of ordinary skill in the art would recognize that Buckberg already delivers the cardioplegic solution and thus just a balloon to cover the aortic root/valve but not the coronary ostia is necessary. It is the examiner's position that one of ordinary skill in the art would be able to accomplish this since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman,* 168 USPQ 177, 179.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Buckberg to deliver a balloon as taught by Samson to block the aortic root and valve to prevent the aortic root from experiencing significant retrograde fluid pressure.

2. Claims 4-6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckberg et al (5,013,296) and Samson et al (6,267,747) as applied to claim 3 above, and further in view of Makower et al (6,638,293).

b. Regarding claims 4-6, 8 and 9, while Buckberg substantially discloses the apparatus as claimed, it does not disclose the membrane being an umbrella that is opened either using a wire or that springs open where both the wire and umbrella are made of nitinol.

However, Makower discloses apparatuses for blocking flow through blood vessels many of them umbrella shaped (figures 4 and 7-9, Col.8 lines 44-48 and Col.1 line 10) structure made of wire and membrane (Col.3 lines 13-15) including nitinol (Col.8 line 65 and Col.9 line 10). The devices may be delivered radially compact such that they self-expand upon delivery (Col.3 line 35) or plastically deformed by application of force or pressure (Col.3 lines 39-42). While Makower does not specifically state the deployment may occur via wire, it does mention linkages to a wire to withdraw the device (Col.3 lines 69-62) via a grab ring (Col.11 lines 26-28). One of ordinary skill in the art would also have knowledge of the embolic devices that use a wire to apply the necessary force to cause the device to expand (such as by a ring that pivots the wires outwardly).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Samson and Buckberg to replace the balloon of Buckberg with an embolic device such as those taught by Makower to occlude the aortic root and aortic valve as they are

both known to occlude blood flow and both are designed to collapse once their use is over.

Response to Arguments

3. Applicant's arguments filed 8/19/2010 have been fully considered but they are not persuasive.

c. Applicant argues that the amendment of adding that the membrane is opened upon emergence form the distal end of the lumen and the membrane is advanced until it covers the aortic valve below the coronary arteries overcomes the art of record. The Examiner is not persuaded as the secondary reference Samson teaches such limitations. Samson discloses using a balloon to cover the aortic valve. From figure 3 it is apparent the balloon is inserted in an uninflated state (which is also common sense). The distal tip is then advanced through the catheter to the appropriate site and opened to cover the aortic valve. While being inflated, the balloon/membrane advances slightly (compare distal ends in figure 3 and 5). The lower portion of the balloon is positioned below the coronary arteries (figure 5).

d. Applicant also seems to be arguing that opening the membrane immediately upon emergence from the distal end of the catheter as opposed to once it is in place is a novel feature. The Examiner is not convinced such a limitation would be allowable subject matter as this seems to be a method design choice. Starting the inflation of the membrane farther up the aortic arch as

opposed to just over the valve does not appear to have any unexpected result or particular advantage.

e. Applicant argues that the combination of Buckberg and Samson do not show or suggest preventing the cardioplegia solution from entering the left ventricle through the aortic valve and trapping the solution above the membrane but below the cross-clamp to force the cardioplegia solution down the coronary arteries. The Examiner does not find Applicant's argument persuasive. Applicant's argument is that neither reference specifically states that it can be used for deficient aortic valves. Samson is a balloon; a balloon is made of one or more membranes. The lower portion of the balloon may be considered either its own membrane or the entire balloon may be considered a single membrane. Regardless, the cardioplegia solution is directed into the coronary ostia and not through the ascending aorta by virtue of the shape of the balloon of Samson (Col.5 lines 59-66 and Col.6 lines 38 and 39). Thus the solution is trapped between a membrane and cross-clamp. One of ordinary skill in the art would recognize that Samson repeatedly refers to the aortic root as being occluded and only occasionally to the valve directly. As the balloon is sized and shaped to occlude the aortic root, the competency of the aortic valve is not an issue for the method and device of Samson, it is capable of treating both. Samson even further suggests conforming the device further to the aortic valve (Col.9 lines 2-4), in addition to shaping the device for the aortic root, the device may be of a compliant material that will take the shape of the valve when inflated (Col.9 lines

17-20), thus the device would be capable of conforming to an incompetent aortic valve.

f. Applicant continues to argues that the aortic valve is not blocked. The Examiner is simply not convinced. Figure 5 is a particularly useful view to show that the membrane of the balloon conforms around the aortic valve to block it. When read as a whole (especially the references cited in the paragraph above) one of ordinary skill in the art would appreciate that Samson shows blocking the aortic valve with a membrane.

g. Applicant argues that Makower does not recognize the problem of aortic valve leakage and thus cannot read upon the current claims. The Examiner is not convinced as the references when read as a whole teach (especially Samson) delivering cardioplegic material only to the coronary arteries. Makower discloses different types of vascular flow blockers. The various species of Makower are all usable with a sufficient or insufficient aortic valve since they block the valve regardless of its structural state.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tatyana Zalukaeva/
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